

EXHIBIT B

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

THE UNITED STATES OF AMERICA *et al.*
ex rel. JULIE LONG,

Plaintiffs,

V.

JANSSEN BIOTECH, INC.,

Defendant.

Civil Action No.
16-12182-FDS

**PLAINTIFF’S SUPPLEMENTAL OBJECTIONS AND RESPONSES TO
DEFENDANT’S INTERROGATORIES 11 TO 16**

Pursuant to Federal Rules of Civil Procedure 26 and 33 and Local Civil Rule 33.1, plaintiff relator Julie Long (“Plaintiff”) hereby objects and responds to defendant Janssen Biotech, Inc.’s (“Defendant”) Interrogatories 11 to 16 (hereinafter, the “Interrogatories”), as follows:

PRELIMINARY STATEMENT

The information contained in the responses set forth below is based upon information and documents currently available to Plaintiff. Plaintiff's investigation and discovery in this matter is not complete. Additional investigation and discovery may provide further information and documents relevant to these responses, as could information and documents obtained from Defendant and/or third parties through additional discovery procedures. The following responses are based upon information known at the time and are given without prejudice to Plaintiff's right to supplement these responses prior to trial or to produce evidence based on subsequently discovered information. Plaintiff's responses are based upon, and therefore limited by, Plaintiff's

present knowledge and, consequently, Plaintiff reserves the right to revise, amend, or supplement these responses as appropriate.

Plaintiff's responses to all or any part of the Interrogatories should not be taken as an admission that: (1) Plaintiff accepts or admits the existence of any fact set forth in or assumed by the interrogatory; (2) Plaintiff has in her possession, custody, or control documents responsive to that interrogatory; or (3) documents responsive to that interrogatory exist. Plaintiff reserves the right to contest Defendant's characterization of any facts, circumstances, or legal obligations as inaccurate.

Plaintiff's responses to all or any part of any interrogatory are not intended to be, and shall not be, a waiver by Plaintiff of all or any part of her objection(s) to that interrogatory.

GENERAL OBJECTIONS

Plaintiff incorporates the following general objections into each of the specific responses set forth below. Plaintiff does not waive any of these general objections in her responses to the specific Interrogatories. Any specific objection made by Plaintiff in no respect limits or modifies these general objections. Plaintiff's objections and responses are made without waiving or intending to waive, but rather intending to preserve and preserving: (1) all objections to competency, relevance, materiality, privilege, and admissibility as evidence for any purpose in this proceeding; (2) the right to object to, on any ground, any demand for further responses to these or any other discovery requests; (3) the right to preserve, prior to providing and as a condition of providing, the confidentiality of any information that may be provided or the subject matter thereof; (4) the right at any time to revise, supplement, clarify, or amend the responses and objections to the Interrogatories, if further factual developments or analysis warrants a

modification, or if additional information is obtained or documents are located that are properly called for by the Interrogatories; and (5) all rights existing at the time of this response.

Plaintiff's specific objections to each interrogatory are in addition to the general limitations and objections set forth in this section. These limitations and objections form a part of the response to each interrogatory and are set forth here to avoid the duplication and repetition of restating them for each response. The absence of a reference to a general objection should not be construed as a waiver of the general objection as to the specific interrogatory.

1. Plaintiff objects to the Interrogatories to the extent that the definitions and instructions seek to impose obligations beyond those required by the Federal Rules of Civil Procedure, Local Civil Rules, or Orders of this Court, or require production of materials or information prohibited by law. Plaintiff will comply with the requirements set forth in the Federal Rules of Civil Procedure, Local Civil Rules, and Orders of this Court, but will not comply with any definition or instruction that seeks to impose a greater requirement. In addition, Plaintiff objects to the Interrogatories insofar as they violate the Court's limitation that each party may serve no more than 25 written interrogatories, including all discrete subparts.

2. Plaintiff objects to the Interrogatories to the extent that they seek information: (a) that is protected from discovery pursuant to the attorney-client privilege, attorney work product doctrine, common-interest privilege, joint prosecutorial privilege, or any other applicable privilege, protection, immunity, or limitation on discovery; (b) that was prepared in anticipation of litigation; or (c) that is otherwise protected from disclosure under the Federal Rules, relevant federal procedural rules, or relevant case law. No information covered by any privilege, protection, immunity, or limitation will be intentionally disclosed. In the event that any such information is disclosed by Plaintiff, such disclosure is inadvertent and does not constitute a

waiver of any privilege, protection, immunity, or limitation from disclosure. Plaintiff reserves the right to demand the return of any privileged or otherwise protected information inadvertently produced during discovery.

3. Plaintiff objects to the Interrogatories to the extent that they purport to require information or production of documents concerning any expert or other person or entity retained by Plaintiff's counsel to assist in the preparation of Plaintiff's case but who will not be designated by Plaintiff as an affiant or witness on the grounds that such disclosure violates the attorney work-product doctrine and is not required by the Federal Rules of Civil Procedure.

4. Plaintiff objects to the Interrogatories to the extent that they seek legal conclusions and/or ultimate factual determinations. Plaintiff objects to the Interrogatories to the extent that they seek to force Plaintiff to prematurely adopt or lock into a legal position.

5. Plaintiff objects to the Interrogatories to the extent that they seek information, documents, or other materials that are within the possession, custody, or control of Defendant, and/or its counsel, and/or that are publicly available, and, therefore, may be accessed by Defendant with less burden than Plaintiff can identify and provide the requested information. In particular, the Interrogatories purport to require Plaintiff to replicate information already provided by Plaintiff to Defendant through the pleadings and during the course of discovery in this action.

6. Plaintiff objects to the Interrogatories to the extent that they seek information not within the possession, custody, or control of Plaintiff, or that are available from a more convenient, more efficient, less burdensome, or less expensive source. Plaintiff's search and responses will be limited to information reasonably in her possession, custody or control.

7. Plaintiff objects to the Interrogatories to the extent that they are not proportional to the needs of the case.

8. Plaintiff objects to the Interrogatories to the extent that they seek information that is not relevant to the claims or defenses of any party to this action, nor reasonably calculated to lead to the discovery of admissible evidence under the Federal Rules or otherwise purport to impose any obligation on Plaintiff beyond that required or permitted by the Federal Rules or the Local Rules, or other rules or practices applicable to cases in this Court.

9. Plaintiff objects to the Interrogatories to the extent that they are overbroad or seek irrelevant information and are therefore unduly burdensome.

10. Plaintiff objects to the Interrogatories to the extent that they are vague or ambiguous and, as such, would require Plaintiffs to speculate as to the meaning of the interrogatory.

11. Plaintiff objects to the Interrogatories to the extent that they prematurely seek information that is required to be disclosed in a pre-trial order, such as the identity of testifying witnesses or exhibits to be used at trial.

12. Plaintiff objects to the Interrogatories to the extent that they seek information that is duplicative, cumulative, and/or redundant of Defendant's requests for the production of documents or other discovery sought or provided in this action.

13. Plaintiff objects to the Interrogatories to the extent that they are compound and contain multiple numbered and unnumbered subparts.

14. Plaintiff objects to the Interrogatories to the extent that Defendant asserts Plaintiff's responses thereto constitute an adoption or acceptance of terms or definitions that Defendant has employed, including to the extent that it seeks to define terms and/or characterize

the evidence or pleadings in this matter. In responding to the Interrogatories, Plaintiff does not adopt, embrace, or accept any term or definition employed by Defendant. To the extent that Plaintiff adopts any terms used by Defendant in the Interrogatories, such adoption is specifically limited to these responses and shall not be construed as an admission. These responses are made based upon Plaintiff's interpretation of words contained in the interrogatory, unless a specific definition or instruction has been agreed upon.

15. Plaintiff objects to the Interrogatories to the extent that they misstate, misdescribe, or misconstrue Plaintiff's claims or allegations.

16. In submitting these responses, Plaintiff expressly reserves the right to object on any ground whatsoever to the use as evidence or any other use of the information provided in this or any other proceeding.

17. Plaintiff objects to the extent the Defendant's Interrogatories are directed to counsel.

18. Plaintiff objects to the Interrogatories to the extent that they seek to impose additional and/or different discovery obligations than those discovery obligations imposed pursuant to any orders entered by the Court and/or any agreements between the Parties regarding the discovery of electronically stored information and/or confidential information.

19. Plaintiff objects to Defendant's definition of the Phase 1 Accounts to the extent that it fails to take into account that certain physician practices within this sample set did business under different names and/or merged with other physician practices during the relevant period. Plaintiff responds below on the understanding that the term Phase 1 Accounts includes the predecessor and successor entities of the physician practices within the sample set.

20. Plaintiff objects to the Interrogatories because Janssen did not comply with the Court's instruction that the parties should seek leave of court before serving additional discovery requests. *See* Sept. 9, 2022 Order (ECF 322) at 5 n.3.

21. Plaintiff's answers are not an admission or agreement that the request is proper or a waiver of an objection, should interrogatories be made for further similar information.

OBJECTIONS AND RESPONSES

INTERROGATORY 11: State the basis for Your contention that the remuneration identified in Your response to Interrogatory No. 10 was a kickback.

RESPONSE TO INTERROGATORY 11:

To the extent that this interrogatory is requesting that Plaintiff state the evidentiary support for each alleged Anti-Kickback Statute violation, Plaintiff objects because it is misusing this interrogatory to improperly attempt to obtain a detailed narrative of Plaintiff's case or pretrial memorandum. Defendant has failed to show why the information requested in this Interrogatory is appropriate or necessary at this stage of the litigation. Also, additional documents that support Plaintiff's claims are in the custody, possession, or control of Defendant and are still in the process of being produced and reviewed.

Subject to the foregoing objections and the general objections, Plaintiff responds as follows: The Anti-Kickback Statute states that "whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person ... to purchase, ... order, ... or recommend purchasing ... or ordering any ... service, or item for which payment may be made in whole or in part under a Federal health care program" shall be guilty of a felony. 42 U.S.C. § 1320a-7b(b)(2). The Anti-Kickback Statute "makes it illegal to offer, pay, solicit or receive

anything *of value* as an inducement to generate business payable by Medicare or Medicaid.” *U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39 (D. Mass. 2011) (quoting Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65372, 65375 (Dec. 19, 1994)); Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35958 (July 29, 1991) (“Congress’s intent in placing the term ‘remuneration’ in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever. The statute’s language makes clear that illegal payments are prohibited beyond merely ‘bribes,’ ‘kickbacks,’ and ‘rebates,’ which were the three terms used in the original 1972 statute.”); *United States v. Regeneron Pharm., Inc.*, Civ. No. 20-11217-FDS, 2020 WL 7130004, at *10 (D. Mass. Dec. 4, 2020). Liability under the Anti-Kickback Statute requires an “intent to induce a referral or recommendation,” and “[a]n intent to induce referrals ... means an intent ‘to gain influence over the reason or judgment’ of the [prescribing] physicians.” *Regeneron*, 2020 WL 7130004, at *8 (quoting *United States v. Medtronic, Inc.*, 189 F. Supp. 3d 259, 268, 271 (D. Mass. 2016)). A person who offers or pays remuneration to a health care provider violates the Anti-Kickback Statute “so long as one purpose of the offer or payment is to induce Medicare or Medicaid patient referrals.” *Id.* (quoting *United States v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000)).

The services and related programs identified in the responses to Interrogatories 2 and 10 (collectively, the “IOI Support”) constitute “remuneration” as that term is used in the Anti-Kickback Statute. Although the meaning of “remuneration” is broader than the term “kickback,” as is commonplace in cases alleging Anti-Kickback Statute violations, Plaintiff uses the terms remuneration and kickbacks interchangeably. Each type of service and related program Defendant offered and provided (directly or indirectly through agents and representatives

including outside consultants) to rheumatology and gastroenterology physician practices including the Phase 1 Accounts (including all owners, shareholders, partners, limited partners, and persons employed by the physician practices) (collectively, “IOI accounts”) had significant value and the value of the package or bundle of services and related programs offered and provided was even greater. In addition, the services and related programs (individually and collectively) had broad and significant independent value beyond Defendant’s drugs Remicade and Simponi ARIA because the IOI Support was not part of the products Remicade and Simponi ARIA and the IOI Support was equally applicable to other infusion drugs and related to the management and operation of the in-office infusion suite where multiple medications can be administered to patients by infusion as well as the physician practice.

Alleged facts and information that support the allegation that the IOI Support was of significant and independent value to the recipient IOI accounts, including the Phase 1 Accounts, include, but are not limited to:

- (A) The business issues addressed through the advice, education, support, and/or assistance Defendant provided to targeted IOI accounts through the IOI Support;
- (B) Many of the IOI Support services and related programs provided to targeted IOI accounts were unbranded, as designated by Defendant;
- (C) Defendant’s special team of employees titled Area Business Specialists (“ABSs”) provided the IOI Support to targeted IOI accounts through in person consultative sessions, live teleconferences, and/or live webinars;
- (D) The ABSs maintained ongoing business relationships with the targeted IOI accounts, during which they regularly monitored and assessed to determine which IOI Support services and related programs would be of the most benefit and value to the IOI accounts and then subsequently delivered such services and related programs;
- (E) The IOI Support services and related programs were frequently selected by the ABSs and/or IOI accounts to address IOI accounts’ specific business needs and practices;
- (F) The IOI Support services and related programs were frequently customized to address the IOI accounts’ specific needs and practices;

- (G) Defendant paid outside consultants to provide many of the IOI Support services and related programs to targeted IOI accounts through in person consultative sessions, live teleconferences, and/or live webinars;
- (H) The ABSs regularly monitored the IOI accounts' progress in implementing the business advice, education, and information the ABSs and outside consultants provided through the IOI Support services and related programs and often assisted the IOI accounts with their implementation of the business advice, education, and information the ABSs and outside consultants provided;
- (I) Many of the IOI Support services and related programs were developed by outside consultants that Defendant paid to develop the services and related programs (including visuals aids, materials, and analytical tools utilized in providing the services and programs);
- (J) Employees regularly communicated concerning the value and benefits that IOI accounts derived from the IOI Support services and related programs;
- (K) Employees frequently called the services and related programs "value adds" or similar terms;
- (L) Recipient IOI accounts communicated about the value and benefits they derived from the IOI Support services and related programs;
- (M) The increased practice and IOI efficiencies and profitability that IOI accounts received as a result of the IOI Support services and related programs;
- (N) The reduction in financial risk that the IOI accounts received as a result of the IOI Support services and related programs;
- (O) The reduction of the overhead costs and burdens IOI accounts received as a result of their receipt of the IOI Support;
- (P) The market value of similar services and advice available from outside consultants;
- (Q) The demand from the targeted IOI accounts for the IOI Support;
- (R) Defendant treated the IOI Support services and related programs as proprietary and confidential and did not disclose to patients, other physician practices, or the United States that it provided the IOI Support to targeted IOI accounts;
- (S) Employees believed that providing the IOI Support gave it a competitive advantage;
- (T) Employees believed that the IOI Support services and related programs generated loyalty to Defendant and its products from recipient IOI accounts;

- (U) Many IOI accounts that received the IOI Support gave ABSs a higher level of access to their physicians and staff than they gave to other drug company representatives;
- (V) The IOI Support and related programs were provided to increase sales or prescriptions of multiple drugs (Remicade and Simponi ARIA) as well as future infusible products that Defendant was developing;
- (W) Defendant provided certain similar types of programs to oncology practices that operated an infusion center as part of their practices;
- (X) Defendant's assertions to the Court in support of its motion for judgment on the pleadings filed on March 14, 2023;
- (Y) Defendant had ABSs and outside consultants promote the infusion business model and/or the buy and bill model to IOI accounts;
- (Z) Defendant had ABSs and outside consultants advise or educate IOI accounts that other infusible products were under development and the opportunity to use their IOI to infuse an increasing number of additional infusible drugs in the future;
- (AA) Defendant closely tracked the SOC programs that the ABSs and outside consultants provided to IOI accounts; and
- (BB) Defendant expended significant sums of money and resources providing the IOI Support over a lengthy period.

The following categories of documents produced in this action, as well as the non-exhaustive list of highly relevant documents produced by Defendant and Xcenda, LLC, set forth in Appendix A, support and/or evidence the above alleged facts and information:

- (A) The visual aids, materials, and analytical tools Defendant had ABSs and outside consultants utilize in providing the IOI Support services and related programs;
- (B) Documents describing the IOI Support services and related programs provided to IOI accounts;
- (C) Documents reporting the amounts Defendant spent developing and providing the IOI Support services and related programs;
- (D) Documents reflecting, concerning, or summarizing statements and feedback from IOI accounts, physicians, practice managers, ABSs, Immunology Specialists, and/or outside consultants in response to surveys, market research, and advisory boards Defendant conducted directly or through outside consultants;

- (E) Documents, including Power Point presentations and scripted questions, utilized for surveys, market research, and advisory boards Defendant conducted concerning the value or benefits, or potential value or potential benefits, of the IOI Support services and related programs;
- (F) Documents reflecting, concerning, or summarizing statements made in communications between employees and IOI accounts that received the IOI Support services and related programs;
- (G) Documents reflecting or concerning communications between employees;
- (H) Documents reflecting, concerning, or summarizing communications between employees and the company's counsel (many of which are currently withheld under an asserted claim of attorney-client privilege);
- (I) Documents reflecting or concerning employees' communications with the Promotional Review Committee;
- (J) Documents reflecting, concerning, or summarizing communications between employees and outside consultants;
- (K) Defendant's and/or outside consultants' assessments of the value of the IOI Support services and related programs;
- (L) The transcript containing testimony and information provided by Susan Bennof during an under oath examination conducted by the U.S. Department of Justice on Dec. 7, 2017;
- (M) Recommendation letters certain recipients of the IOI Support wrote on Plaintiff's behalf;
- (N) Defendant's contracts and documents reflecting summaries of Defendant's contracts with outside consultants to provide IOI Support, including the fees Defendant paid to the outside consultants to provide the IOI Support services and related programs;
- (O) Documents reflecting or concerning employees' requests for approval and subsequent approvals to contract with outside consultants to provide IOI Support services and related programs to IOI accounts;
- (P) Defendant's and outside consultants' documents concerning the IOI Support services and related programs provided to IOI accounts;
- (Q) Defendant's contracts and documents reflecting summaries of Defendant's contracts with outside consultants to develop and/or update IOI Support programs, including the fees Defendant paid to the outside consultants to develop and/or update the IOI Support programs;

- (R) Documents reflecting or concerning employees' requests for approval and subsequent approvals to contract with outside consultants to develop and/or update IOI Support programs;
- (S) Defendant's contracts and documents reflecting summaries of Defendant's contracts with outside consultants to conduct market research of physicians, practice managers, nurses, and other staff from physician practices concerning the value or potential value or benefit or potential benefit of IOI Support programs;
- (T) Documents reflecting or concerning defendant's internal requests for approval and subsequent approvals to contract with outside consultants to conduct market research of physicians, practice managers, nurses, and other staff from IOI accounts concerning the value or potential value or benefits or potential benefits of the IOI Support services and related programs;
- (U) Documents reflecting or concerning the results of market research, surveys, or advisory boards Defendant conducted or paid outside consultants to conduct concerning the value or potential value or benefit or potential benefit of the IOI Support and related programs to IOI accounts;
- (V) Documents reflecting or concerning communications by employees and/or outside consultants concerning the competitive advantage and/or customer loyalty Defendant obtained by providing the IOI Support services and related programs to targeted IOI accounts;
- (W) Documents and data that tracked and/or summarized the IOI Support programs ABSs and outside consultants provided to IOI accounts;
- (X) Attendance sheets ABSs and/or outside consultants completed and submitted to track the attendees of the SOC programs;
- (Y) Defendant's court filings in support of its motion for judgment on the pleadings filed on March 14, 2023;
- (Z) Documents and information concerning practice management advice and consultative services available to physician practices that were similar to the IOI Support services and related programs that Defendant provided through ABSs and outside consultants;
- (AA) Documents describing the ABS position and the ABSs' responsibilities;
- (BB) Documents describing the ABSs' managers' positions and their responsibilities;
- (CC) Defendant's documents reflecting or concerning training ABSs received concerning performing their responsibilities, including providing IOI Support services and related programs, to IOI accounts;

- (DD) Documents concerning ABSs' and Immunology Specialists' requests for outside consultants to provide SOC programs to selected IOI accounts;
- (EE) Documents reflecting that Defendant provided certain similar types of IOI Support programs to oncology practices that operated an infusion center as part of their practices;
- (FF) Documents reflecting or concerning ABSs' business plans, performance reviews and evaluations;
- (GG) Documents reflecting or concerning ABSs' managers' business plans and performance reviews and evaluations;
- (HH) Defendant's answers to Plaintiff's interrogatories; and
- (II) Defendant's written answers to Plaintiff's deposition questions.

Additionally, from performing the responsibilities of an Area Business Specialist, Plaintiff has direct knowledge of the significant and independent value of the IOI Support to the recipient IOI accounts, including the Phase 1 Accounts.

Information from physicians with experience operating an IOI, including Jill Cramer, MD, and Seth Tatel, MD, support and/or evidence the significant and independent value of the IOI Support.

Information concerning consulting firms that provide physician practices consultative services that are similar to many of the IOI Support services and related programs Defendant provided to targeted IOI accounts, including, but not limited to, AmerisourceBergen, DAS Health, Deloitte Consulting, HMA Consulting, Infinity Infusion Solutions, Infusion Consultant Services and Accreditation Resources (Paula Zelle), Innovative Healthcare Solutions, Huizenga Systems Consulting (Mark Huizenga), McKesson Business Advisors, Practice & Liability Consultants, Rock Consulting Inc., Specialty Networks, Specialty Practice Network (a/k/a IPN Solutions; International Rheumatology Network), Visante, WeInfuse, Woodcock & Associates,

Zetter Healthcare Management Consultants, support and/or evidence the significant and independent value of IOI Support.

One of Defendant's objectives or purposes in offering and providing the IOI Support was to induce health care providers associated with the recipient IOI accounts, including the Phase 1 Accounts, to prescribe and infuse Remicade and/or Simponi ARIA to patients, including Medicare beneficiaries.

Alleged facts and information that support the allegation that one of Defendant's objectives or purposes in offering and providing the IOI Support to the recipient IOI accounts, including the Phase 1 Accounts, was to induce health care providers associated with the IOI accounts to prescribe and infuse Remicade and/or Simponi ARIA to Medicare beneficiaries, include, among others:

- (A) Employees created strategic imperatives, objectives, and business plans that included: (i) developing and opening new IOIs; (ii) influencing and/or assisting IOI accounts to continue operating their IOI and/or grow the volume of infusions performed at their IOI; (iii) influencing IOI accounts to maintain and grow their sales or prescriptions of Remicade and/or Simponi ARIA; and/or (iv) cause IOI accounts to favor Defendant and its drugs Remicade and/or Simponi ARIA so as to prescribe less of the drugs that compete with Remicade and Simponi ARIA (infusible drugs and self-administered drugs);
- (B) Employees regularly communicated internally that the one of the purposes of providing the IOI Support and related programs was to: (i) develop and open new IOIs; (ii) influence and/or assist IOI accounts to continue operating their IOI and/or grow the volume of infusions performed at their IOI; (iii) induce IOI accounts to maintain and grow their sales or prescriptions of Remicade and/or Simponi ARIA; and/or (iv) cause IOI accounts to favor Defendant and its drugs Remicade and/or Simponi ARIA and prescribe less of the drugs that compete with Remicade and Simponi ARIA (infusible drugs and self-administered drugs);
- (C) Employees' and outside consultants' descriptions of the purpose of providing the IOI Support services and related programs;
- (D) The business issues addressed through the advice, education, support, and/or assistance Defendant provided to targeted IOI accounts through the IOI Support;

- (E) Defendant only provided the IOI Support to select IOI accounts;
- (F) The volume of IOI Support that Defendant offered and provided to IOI accounts was based on IOI accounts' sales or prescription volume of Remicade and/or Simponi ARIA or IOI accounts' potential sales or prescription volume of Remicade and/or Simponi ARIA;
- (G) In selecting the IOI accounts to which it would provide IOI Support, Defendant's SOC marketing team, sales analytics team, ABSs' managers, and ABSs identified physicians whom they believed could be influenced to increase their prescriptions of Remicade and/or Simponi ARIA by providing the IOI Support and related programs;
- (H) Defendant's SOC marketing team, sales analytics team, ABSs' managers, and ABSs monitored the impact of the IOI Support services and related programs on recipient IOI accounts' sales or prescriptions of Remicade and Simponi ARIA;
- (I) When requesting that an outside consultant provide IOI Support programs to a selected IOI account, the ABSs and/or Immunology Specialists were required to explain why they believed that having the outside consultant provide the IOI Support program would result in increased prescriptions of Remicade and/or Simponi ARIA by the IOI account;
- (J) Defendant internally characterized the IOI Support services and related programs as "promotional";
- (K) Defendant set Remicade and/or Simponi ARIA sales goals for ABSs and the ABSs' managers;
- (L) A portion of ABSs' and the ABSs' managers' compensation was based on the growth in sales of Remicade and Simponi ARIA within the ABSs' accounts and on the number of new IOIs the ABSs' assisted in developing and opening;
- (M) ABSs' managers directed that when providing IOI Support and related programs to IOI accounts ABSs' should request: (i) prescriptions of Remicade and/or Simponi ARIA; and/or (ii) an increase in the volume of infusions performed;
- (N) Defendant's descriptions of the purpose of providing the IOI Support services and related programs to IOI accounts;
- (O) Employees believed that providing the IOI Support services and related programs gave Defendant a competitive advantage;
- (P) The ABSs' menu of objectives for their Management By Objective ("MBO") plans as well as the menu of tactics to achieve the objectives, including providing IOI Support and related programs;

- (Q) Defendant analyzed its return on providing the IOI Support and related programs to IOI accounts;
- (R) Defendant provided the IOI Support and related programs to IOI accounts' business managers and executives in addition to physicians within the IOI accounts; and
- (S) Defendant provided the IOI Support and related programs to targeted physicians while they were performing fellowships in an effort induce them to open an IOI and prescribe and infuse Remicade and/or Simponi ARIA when they eventually go into private practice.

The following categories of documents produced in this action, as well as the non-exhaustive list of highly relevant documents produced by Defendant and Xcenda, LLC, set forth in Appendix A, support and/or evidence the above alleged facts and information:

- (A) Documents reflecting, concerning, or summarizing the employees' strategic imperatives, objectives, and business plans that included: (i) developing and opening new IOIs; (ii) influencing and/or assisting IOI accounts to continue operating their IOI and/or grow the volume of infusions performed at their IOI; (iii) influencing IOI accounts to maintain and grow their sales or prescriptions of Remicade and/or Simponi ARIA; and/or (iv) cause IOI accounts to favor Defendant and its drugs Remicade and/or Simponi ARIA and prescribe less of the drugs that compete with Remicade and Simponi ARIA (infusible drugs and self-administered drugs);
- (B) Documents reflecting or concerning employees' internal communications that the one of the purposes of providing the IOI Support and related programs was to: (i) develop and open new IOIs; (ii) influence and/or assist IOI accounts to continue operating their IOI and/or grow the volume of infusions performed at their IOI; (iii) induce IOI accounts to maintain and grow their sales or prescriptions of Remicade and/or Simponi ARIA; and/or (iv) cause IOI accounts to favor Defendant and its drugs Remicade and/or Simponi ARIA and prescribe less of the drugs that compete with Remicade and Simponi ARIA (infusible drugs and self-administered drugs);
- (C) Documents reflecting or concerning employees' and outside consultants' descriptions of the purpose of providing the IOI Support;
- (D) The visual aids, materials, and analytical tools Defendant had ABSs and outside consultants utilize in providing the IOI Support services and related programs;
- (E) Documents describing the IOI Support services and related programs provided to IOI accounts;
- (F) Documents reporting the amounts Defendant spent developing and providing the IOI Support services and related programs;

- (G) Documents reflecting that Defendant focused on providing the IOI Support to targeted IOI accounts;
- (H) Documents reflecting that the volume of IOI Support services and related programs that Defendant offered and provided to IOI accounts was based on IOI accounts' sales or prescription volume of Remicade and/or Simponi ARIA or IOI accounts' potential sales or prescription volume of Remicade and/or Simponi ARIA;
- (I) Documents reflecting that in selecting the IOI accounts to which it would provide IOI Support and related programs, Defendant's SOC marketing team, sales analytics team, ABSs' managers, and ABSs identified physicians whom it believed could be influenced to increase their prescriptions of Remicade and/or Simponi ARIA by providing the IOI Support and related programs;
- (J) ABSs' managers' and ABSs' call plans and call frequency plans analyzing and/or selecting which IOI accounts would receive IOI Support services and related programs and how frequently they would receive the services and programs;
- (K) Documents analyzing the impact of the IOI Support services and related programming that ABSs and/or outside consultants provided to IOI accounts had on sales or prescriptions of Remicade and/or Simponi ARIA;
- (L) SOC program request forms where the ABSs and/or Immunology Specialists explained why they believed that having the outside consultant provide the SOC program would result in increased prescriptions of Remicade and/or Simponi ARIA by the IOI account;
- (M) Documents reflecting that employees internally characterized the IOI Support services and related SOC programs as "promotional";
- (N) Documents reflecting or concerning Remicade and/or Simponi ARIA sales goals for ABSs and the ABSs' managers;
- (O) Documents reflecting that a portion of ABSs' and the ABSs' managers' compensation was based on growth in sales of Remicade and Simponi ARIA within the ABSs' accounts and on the number of new IOIs the ABSs' assisted in developing and opening;
- (P) Documents reflecting or concerning the sales commissions and/or bonuses ABSs were paid for: (i) maintaining and growing sales of Remicade and/or Simponi ARIA within IOI accounts in their territories; (ii) assisting in developing and opening new IOIs; and (iii) achieving the objectives in their MBOs.
- (Q) Documents reflecting that ABSs' managers directed that after providing IOI Support and related programs to IOI accounts ABSs' should request: (i) prescriptions of Remicade and/or Simponi ARIA; and/or (ii) increase to volume of infusions performed;

- (R) Documents reflecting employees' descriptions of the purpose of providing the IOI Support to IOI accounts;
- (S) Documents reflecting that employees believed that the IOI Support services and related programs were a competitive advantage;
- (T) The ABSs' MBO plans including the ABSs' MBO "Results" reports;
- (U) Documents reflecting or concerning analyses concerning the company's return on providing the IOI Support and related programs to IOI accounts;
- (V) Documents reflecting that Defendant provided the IOI Support and related programs to IOI accounts' business managers and executives in addition to physicians within the IOI accounts;
- (W) Documents reflecting that Defendant provided the IOI Support programs to targeted physicians while they were performing fellowships in an effort influence them to open an IOI and prescribe and infuse Remicade and/or Simponi ARIA when they eventually go into private practice;
- (X) Documents reflecting, concerning, or summarizing statements and feedback from IOI accounts, physicians, practice managers, ABSs, Immunology Specialists, and/or outside consultants in response to surveys, market research, and advisory boards Defendant conducted directly or through outside consultants;
- (Y) Documents, including presentations and scripted questions, utilized to conduct surveys, market research, and advisory boards concerning the value or benefits or potential value or potential benefits of the IOI Support services and related programs;
- (Z) Documents reflecting, concerning, or summarizing statements made in communications between employees and IOI accounts that received the IOI Support;
- (AA) Documents reflecting communications between employees;
- (BB) Documents reflecting, concerning, or summarizing communications between employees and the company's counsel (many of which are currently withheld under an asserted claim of attorney-client privilege);
- (CC) Documents reflecting or concerning employees' communications with its Promotional Review Committee;
- (DD) Documents reflecting, concerning, or summarizing communications between employees and outside consultants;
- (EE) The transcript containing testimony and information provided by Susan Bennof during an examination under oath conducted by the U.S. Department of Justice on Dec. 7, 2017;

- (FF) Defendant's contracts and documents reflecting summaries of Defendant's contracts with outside consultants to provide IOI Support services and programs, including the fees Defendant paid to the outside consultants to provide the services and programs;
- (GG) Documents reflecting or concerning employees' requests for approval and subsequent approvals to contract with outside consultants to provide IOI Support services and programs to IOI accounts;
- (HH) Documents concerning the IOI Support services and related programs provided to IOI accounts;
- (II) Defendant's contracts and documents reflecting summaries of Defendant's contracts with outside consultants to develop and/or update IOI Support programs, including the fees Defendant paid to the outside consultants to develop and/or update programs;
- (JJ) Documents reflecting or concerning employees' requests for approval and subsequent approvals to contract with outside consultants to develop and/or update IOI Support programs;
- (KK) Defendant's contracts and documents reflecting summaries of Defendant's contracts with outside consultants to conduct market research of physicians, practice managers, nurses, and other staff from physician practices concerning the value or potential value or benefits or potential benefits of IOI Support;
- (LL) Documents reflecting or concerning employee's internal requests for approval and subsequent approvals to contract with outside consultants to conduct market research of physicians, practice managers, nurses, and other staff from IOI accounts concerning the value or potential value or benefits or potential benefits of the IOI Support services and related programs;
- (MM) Documents concerning the results of market research or advisory boards Defendant conducted or paid outside consultants to conduct concerning the value or potential value or benefit or potential benefit of IOI Support services and programs to IOI accounts;
- (NN) Documents reflecting or concerning communications by employees and/or outside consultants concerning the competitive advantage and/or customer loyalty Defendant obtained by providing the IOI Support services and related programs to targeted IOI accounts;
- (OO) Documents and data that tracked and/or summarized the IOI Support programs ABSs and outside consultants provided to IOI accounts;
- (PP) Defendant's court filings in support of its motion for judgment on the pleadings filed on March 14, 2023;

- (QQ) Documents describing the ABS position and the ABSs' responsibilities;
- (RR) Documents describing the ABSs' managers' positions and their responsibilities;
- (SS) Documents reflecting or concerning training ABSs' received concerning performing their responsibilities, including providing IOI Support services and related programs, to IOI accounts;
- (TT) Documents reflecting that Defendant provided certain similar types of IOI Support programs to oncology practices that operated an infusion center as part of their practices;
- (UU) Documents reflecting or concerning ABSs' performance reviews and evaluations;
- (VV) Documents reflecting or concerning ABSs' managers' business plans and performance reviews and evaluations;
- (WW) Defendant's answers to Plaintiff's interrogatories; and
- (XX) Defendant's written answers to Plaintiff's deposition questions.

Additionally, from performing the responsibilities of an Area Business Specialist, Plaintiff has direct knowledge that one of Defendant's purposes and objectives in providing the IOI Support to the recipient IOI accounts, including the Phase 1 Accounts, was to induce health care providers associated with the IOI accounts to prescribe and infuse Remicade and/or Simponi ARIA to patients, including Medicare beneficiaries.

Defendant's provision of the IOI Support to the select recipient IOI accounts, including the Phase 1 Accounts, resulted in health care providers associated with the IOI accounts prescribing and infusing Remicade and/or Simponi ARIA to Medicare beneficiaries and subsequently billing and receiving payment from Medicare for the Remicade and/or Simponi ARIA infused and the related infusion procedures.

Alleged facts and information that support the allegation that the IOI Support resulted in prescriptions and infusions of Remicade and/or Simponi ARIA to Medicare beneficiaries and the corresponding false claims for payment include, but are not limited to:

- (A) Employees achieved their strategic imperatives, objectives, and business plans that included: (i) developing and opening new IOIs; (ii) influencing and/or assisting IOI accounts to continue operating their IOI and/or grow the volume of infusions performed at their IOI; (iii) influencing IOI accounts to maintain and grow their sales or prescriptions of Remicade and/or Simponi ARIA; and/or (iv) causing IOI accounts to favor Defendant and its drugs Remicade and/or Simponi ARIA and prescribe less of the drugs that compete with Remicade and Simponi ARIA (infusible drugs and self-administered drugs);
- (B) Employees regularly communicated internally that providing the IOI Support and related programs enabled Defendant to: (i) develop and open new IOIs; (ii) influence and/or assist IOI accounts to continue operating their IOI and/or grow the volume of infusions performed at their IOI; (iii) induce IOI accounts to maintain and grow their sales or prescriptions of Remicade and/or Simponi ARIA; and/or (iv) cause IOI accounts to favor Defendant and its drugs Remicade and/or Simponi ARIA and prescribe less of the drugs that compete with Remicade and Simponi ARIA (infusible drugs and self-administered drugs);
- (C) Defendant incurred significant expenses to provide the IOI Support and related programs to targeted IOI accounts because it resulted in sales of Remicade and Simponi ARIA;
- (D) Defendant made the business decision to provide the IOI Support and related programs to targeted IOI accounts while knowing that this conduct was unlawful because providing the IOI Support and related programs to targeted IOI accounts resulted in significant sales or prescriptions of Remicade and/or Simponi ARIA;
- (E) Employees' communications that the provision of IOI Support to IOI accounts resulted in sales or prescriptions of Remicade and Simponi ARIA;
- (F) Communications by IOI accounts that the receipt of the IOI Support resulted in sales or prescriptions of Remicade and Simponi ARIA;
- (G) Communications by outside consultants that providing the IOI Support to IOI accounts resulted in sales or prescriptions of Remicade and Simponi ARIA;
- (H) Employees' determinations from analyses concerning the impact that providing IOI Support to IOI accounts had on sales or prescriptions of Remicade and Simponi ARIA;
- (I) The temporal proximity between the receipt of the IOI Support and IOI accounts' prescriptions and infusions of Remicade and/or Simponi ARIA;
- (J) Defendant's analyses showed that providing the IOI Support services and related programs resulted in sales or prescription of Remicade and Simponi by the recipient IOI accounts;

- (K) The bonuses, awards, or commissions that ABSs received showed that providing the IOI Support services and related programs resulted in sales or prescriptions of Remicade and Simponi ARIA by the recipient IOI accounts;
- (L) The achievement of the sales goals that were set for ABSs showed that providing the IOI Support services and related programs resulted in sales or prescription of Remicade and Simponi by the recipient IOI accounts;
- (M) When providing IOI Support and related programs to IOI accounts ABSs' requested and obtained: (i) prescriptions of Remicade and/or Simponi ARIA; and/or (ii) an increase in volume of infusions performed;
- (N) In deciding whether an IOI account would receive IOI Support from an ABS and/or outside consultant, Defendant considered whether the provision of the IOI Support would result in sales or prescriptions of Remicade and/or Simponi ARIA;
- (O) In selecting the IOI accounts to which it would provide IOI Support, Defendant's SOC marketing team, sales analytics team, the ABSs' managers, and the ABSs identified physicians whom it believed it could influence to increase their prescriptions of Remicade and/or Simponi ARIA by providing the IOI Support and related programs;
- (P) ABSs prepared business plans in which causing sales of Remicade and/or Simponi ARIA was one of the objectives;
- (Q) Included among the ABSs responsibilities was growing sales of Remicade and Simponi ARIA;
- (R) Included among the ABSs' required competencies was the ability to influence physician decision making;
- (S) Defendant's assistance in helping physician practices develop and open an IOI after which the physician practices prescribed and infused Remicade and/or Simponi ARIA;
- (T) Defendant's assistance in helping physician practices continue operating an IOI – also known as sustaining the infusion model – influencing the physician practices to continue prescribing Remicade and/or Simponi ARIA;
- (U) Providing the IOI Support services and related programs gave Defendant a competitive advantage;
- (V) Providing the IOI Support services and related programs caused the recipient IOI accounts to favor Defendant's drugs Remicade and Simponi ARIA and representatives;
- (W) A substantial percentage of IOI accounts' patients were Medicare beneficiaries;
- (X) Defendant reviewed what portion of IOI accounts' patients were Medicare beneficiaries;

- (Y) It was foreseeable that the IOI accounts that received the IOI Support services and related programs would submit false claims for payment or reimbursement to Medicare for the Remicade, Simponi ARIA, and related infusion procedures that resulted from or were caused by Defendant's provision of the IOI Support services and related programs.

The following categories of documents produced in this action, as well as the non-exhaustive list of highly relevant documents produced by Defendant and Xcenda, LLC, set forth in Appendix A, support and/or evidence the above alleged facts and information:

- (A) Documents reflecting, concerning, or summarizing employees' achievement of their strategic imperatives, objectives, and business plans that included: (i) developing and opening new IOIs; (ii) influencing and/or assisting IOI accounts to continue operating their IOI and/or grow the volume of infusions performed at their IOI; (iii) influencing IOI accounts to maintain and grow their sales or prescriptions of Remicade and/or Simponi ARIA; and/or (iv) causing IOI accounts to favor Defendant and its drugs Remicade and/or Simponi ARIA and prescribe less of the drugs that compete with Remicade and Simponi ARIA (infusible drugs and self-administered drugs);
- (B) Documents reflecting or concerning employees' internal communications that providing the IOI Support and related programs enabled Defendant to: (i) develop and open new IOIs; (ii) influence and/or assist IOI accounts to continue operating their IOI and/or grow the volume of infusions performed at their IOI; (iii) induce IOI accounts to maintain and grow their sales or prescriptions of Remicade and/or Simponi ARIA; and/or (iv) cause IOI accounts to favor Defendant and its drugs Remicade and/or Simponi ARIA and prescribe less of the drugs that compete with Remicade and Simponi ARIA (infusible drugs and self-administered drugs);
- (C) Documents reflecting or concerning the significant expenses Defendant incurred to provide the IOI Support to targeted IOI accounts for several years;
- (D) Documents reflecting, concerning, or referencing analyses concerning the company's return on providing the IOI Support and related programs to IOI accounts;
- (E) Documents reflecting, concerning, or summarizing analyses concerning the impact that the IOI Support the ABSs and/or outside consultants provided to IOI accounts had on sales or prescriptions of Remicade and/or Simponi ARIA;
- (F) Documents reflecting, concerning, or summarizing analyses that showed that providing the IOI Support services and related programs resulted in sales or prescription of Remicade and Simponi by the recipient IOI accounts;
- (G) Documents reflecting or concerning the achievement of Remicade and/or Simponi ARIA sales goals by ABSs and the ABSs' managers;

- (H) Documents reflecting or concerning the sales commissions and/or bonuses ABSs were paid for: (i) maintaining and growing sales of Remicade and/or Simponi ARIA within IOI accounts in their territories; (ii) assisting in developing and opening new IOIs; and (iii) achieving objectives in their MBOs.
- (I) Documents reflecting that, in response to ABSs' requests, IOI accounts committed to: (i) prescribing Remicade and/or Simponi ARIA to additional patients; and/or (ii) increasing to volume of infusions the account would perform;
- (J) Documents reflecting that employees believed that the IOI Support was a competitive advantage;
- (K) The ABSs' MBO plans including the ABSs' MBO "Results" reports;
- (L) Documents reflecting, concerning, or summarizing statements and feedback from IOI accounts, physicians, and practice managers that the receipt of the IOI Support resulted in the IOI account increasing the volume of infusions it would perform including infusion of Remicade and/or Simponi ARIA;
- (M) Documents reflecting, concerning, or summarizing statements made in communications between employees and the select IOI accounts that received the IOI Support;
- (N) Documents reflecting or concerning communications between employees;
- (O) Documents reflecting, concerning, or summarizing communications between employees and the company's counsel (many of which are currently withheld under an asserted claim of attorney-client privilege);
- (P) Documents reflecting or concerning employees' communications that the provision of IOI Support services and related programs to IOI accounts resulted in sales or prescriptions of Remicade and Simponi ARIA;
- (Q) Documents reflecting or concerning communications by IOI accounts that the receipt of IOI Support resulted in sales or prescriptions of Remicade and Simponi ARIA;
- (R) Documents reflecting or concerning communications by outside consultants that providing IOI Support to IOI accounts resulted in sales or prescriptions of Remicade and Simponi ARIA;
- (S) The transcript containing testimony and information provided by Susan Bennof during an examination under oath conducted by the U.S. Department of Justice on Dec. 7, 2017;
- (T) Documents concerning the results of market research or advisory boards Defendant conducted or paid outside consultants to conduct;

- (U) Documents reflecting or concerning communications by employees and/or outside consultants concerning the competitive advantage and/or customer loyalty Defendant obtained by providing the IOI Support to targeted IOI accounts;
- (V) Documents reflecting or concerning training ABSs received concerning performing their responsibilities, including providing IOI Support to targeted IOI accounts to increase sales of Remicade and/or Simponi ARIA;
- (W) Documents reflecting or concerning ABSs' business plans, performance reviews, and evaluations;
- (X) Documents reflecting or concerning ABSs' managers' business plans and performance reviews and evaluations;
- (Y) Documents reflecting or concerning the percentage of IOI accounts' patients who were Medicare beneficiaries;
- (Z) Documents reflecting or concerning the process through which IOI accounts request reimbursement from Medicare for Remicade and Simponi ARIA prescribed and infused to Medicare beneficiaries;
- (AA) Documents and CMS claims data showing the temporal proximity between the receipt of the IOI Support and IOI accounts' prescriptions and infusions of Remicade and/or Simponi ARIA;
- (BB) Documents describing the ABS position and the ABSs' responsibilities;
- (CC) Documents describing the competencies of the ABS position;
- (DD) Documents describing the ABSs' managers' positions and their responsibilities;
- (EE) Documents that reflect that Defendant monitored sales or prescriptions of Remicade and/or Simponi ARIA by the targeted IOI accounts to which it provided the IOI Support.

From performing the responsibilities of an Area Business Specialist, Plaintiff has direct knowledge that Defendant's IOI Support resulted in health care providers associated with the recipient IOI accounts, including the Phase 1 Accounts, prescribing and infusing Remicade and/or Simponi ARIA to Medicare beneficiaries and subsequently billing Medicare for the Remicade and/or Simponi ARIA infused and related infusion procedures.

Defendant acted voluntarily in providing the IOI Support to the recipient IOI accounts, including the Phase 1 accounts, and knew that it was unlawful to provide IOI Support that had significant and independent value to the recipient IOI accounts with the objective to induce the recipient IOI accounts to prescribe and infuse Remicade and Simponi ARIA to Medicare beneficiaries.

Alleged facts and information that support the allegation that Defendant acted knowingly and willfully in providing the IOI Support to the recipient IOI accounts include, but are not limited to:

- (A) The provision of the IOI Support services and related programs violated the Anti-Kickback Statute and False Claims Act;
- (B) Defendant made the business decision to provide the IOI Support and related programs to targeted IOI accounts for several years while knowing that this conduct was wrongful or unlawful because providing the IOI Support and related programs to targeted IOI accounts resulted in significant sales or prescriptions of Remicade and Simponi ARIA;
- (C) The provision of the IOI Support services and related programs violated or did not comply with Defendant's compliance policies and/or guidance documents or "Brightlines" from its legal counsel;
- (D) Defendant did not seek an advisory opinion from the U.S. Department of Health and Human Services Office of Inspector General regarding whether providing the IOI Support services and related programs to IOI accounts violated the Anti-Kickback Statute;
- (E) Defendant claims it relied on advisory opinions the U.S. Department of Health and Human Services Office of Inspector General provided to other companies concerning materially different marketing strategies;
- (F) Defendant understood that providing services that have independent value to health care providers where one purpose is to induce the health care providers to prescribe its products to patients covered by Medicare violates the Anti-Kickback Statute;
- (G) Defendant understood that Medicare does not reimburse or cover items and services resulting from conduct that violates the Anti-Kickback Statute;
- (H) Defendant is asserting the attorney-client privilege to prevent disclosure and review of its attorneys' legal analyses and the legal advice the attorneys provided concerning whether

providing the IOI Support to physician practices violated the Anti-Kickback Statute; Plaintiff believes that Defendant is asserting the attorney-client privilege to prevent disclosure and review of its attorneys' legal analyses and legal advice because the analyses and advice show that Defendant knew that providing the IOI Support services and related programs to IOI accounts was unlawful;

- (I) Defendant had employees, including attorneys, compliance, and regulatory employees, whitewash or edit internal materials concerning its strategy to provide IOI Support services and related programs to targeted IOI accounts in an effort to conceal that Defendant was engaging in illegal conduct;
- (J) Defendant's attorneys reviewed and/or were aware of the SOC marketing department's strategic imperatives and objectives for growing sales of Remicade and/or Simponi ARIA and the tactics utilized to achieve the objectives including providing the IOI Support services and related programs to targeted IOI accounts;
- (K) Multiple legal actions have been brought against Defendant and/or its parents, subsidiaries, or corporate affiliates for defrauding the Federal healthcare programs;
- (L) Multiple legal actions have been brought against Defendant and/or its parents, subsidiaries, or corporate affiliates for violating the Anti-Kickback Statute;
- (M) In other legal actions, Defendant and/or its parents, subsidiaries, or corporate affiliates have been found to have violated the Anti-Kickback Statute and/or settled Anti-Kickback violation claims.
- (N) Defendant was subject to Corporate Integrity Agreements as a result of its and/or its parents, subsidiaries, or corporate affiliates' prior illegal conduct in promoting drugs;
- (O) Defendant monitored other legal actions brought against drug manufacturers for violating the Anti-Kickback Statute for providing product-related services that had independent value.
- (P) Defendant identified providing certain IOI Support services and related programs as compliance risks;
- (Q) Defendant did not report the IOI Support services and related programs provided to IOI accounts or their value to the Centers for Medicare & Medicaid Services as required under 42 C.F.R. § 403.904 and 42 U.S.C. § 1320a-7h;
- (R) Defendant concealed from patients of the targeted IOI accounts that received the IOI Support services and related programs that it was furnishing the services to their health care providers;

- (S) Employees raised concerns regarding whether providing the IOI Support services and related programs were lawful or complied with Defendant's internal policies and guidance concerning compliance with the Anti-Kickback Statute;
- (T) Defendant provided the IOI Support services and related programs voluntarily and intentionally, not because of a mistake or accident.
- (U) Defendant knew that the claims for payment for Remicade, Simponi ARIA, and the related infusion procedures that the recipients of the IOI Support services and related programs submitted to Medicare were false because: (i) the claims for payment resulted from Defendant's provision of illegal remuneration in violation of the Anti-Kickback Statute; (ii) in the claims, the health care providers falsely represented to Medicare that they had not received illegal remuneration and that they had complied with the Anti-Kickback Statute in providing and billing for the Remicade, Simponi ARIA, and related infusions; and (iii) the health care providers had falsely certified in their provider enrollment agreements with Medicare that they would comply with the Anti-Kickback Statute.
- (V) Defendant knew that compliance with the Anti-Kickback Statute is a requirement for coverage and reimbursement for drugs and services by Medicare and that Medicare would not pay or reimburse the recipients of the IOI Support for billed Remicade, Simponi ARIA, or the related infusion procedures if it knew that the health care providers received the illegal remuneration from Defendant in violation of the Anti-Kickback Statute.

The following categories of documents produced in this action, as well as the non-exhaustive list of highly relevant documents produced by Defendant, set forth in Appendix A, support and/or evidence the above alleged facts and information:

- (A) Documents concerning guidance and policies from Defendant's legal counsel regarding compliance with the Anti-Kickback Statute;
- (B) Documents concerning guidance and policies from Defendant's compliance department regarding compliance with the Anti-Kickback Statute;
- (C) Documents and materials created for meetings in which legal counsel and/or compliance employees provided employees and/or outside consultants guidance concerning conduct that violates the Anti-Kickback Statute and/or False Claims Act;
- (D) Documents reflecting, concerning, or summarizing communications between employees and the company's counsel (many of which are currently withheld under an asserted claim of attorney-client privilege);

- (E) The Corporate Integrity Agreements between the Office of Inspector General of the Department of Health and Human Services and Defendant, including any of Defendant's parents, subsidiaries, or affiliates;
- (F) Documents concerning compliance risks identified as part of the Risk Assessment and Mitigation Planning (RAMP) program;
- (G) Documents showing the changes, comments, and edits that employees from compliance, and regulatory made to internal documents concerning the provision of the IOI Support to physician practices;
- (H) Documents showing that Defendant's legal counsel made changes and edited internal documents concerning the provision of the IOI Support to physician practices;
- (I) Documents and data concerning Defendant's decision to not report the value of the IOI Support services and related programs it provided to IOI account to the Centers for Medicare & Medicaid Services under 42 C.F.R. § 403.904 and 42 U.S.C. § 1320a-7h;
- (J) Documents reflecting or concerning employees' communications expressing concerns related to the legality of providing the IOI Support services and related programs; and
- (K) Defendant's privilege logs.

The following witnesses provided deposition testimony that supports and/or evidences the allegations and information that: (a) the IOI Support was of significant and independent value to the recipient IOI accounts, including the Phase 1 Accounts; (b) one of Defendant's purposes or objectives in providing the IOI Support was to induce health care providers associated with the recipient IOI accounts to prescribe and infuse Remicade and Simponi ARIA to patients, including Medicare beneficiaries; (c) Defendant's provision of the IOI Support resulted in health care providers associated with the recipient IOI accounts prescribing and infusing Remicade and/or Simponi ARIA to Medicare beneficiaries; and/or (d) Defendant acted knowingly and willfully in providing the IOI Support to the recipient IOI accounts: Janice Babia-Ramos; Larry Conley; Tom Cornely; Marti Heckman; Freddy Jimenez; Jim Knepp; Thao Marzullo; Scott Shelhamer; Karen Trahan; Michelle Walls; Paul Wickmann; Mike Wolfe; Xcenda, LLC; Chris Zalesky; and Lou Zambelli. Additional depositions are scheduled to be taken.

For additional information concerning the alleged facts and information supporting her claim that Defendant violated the Anti-Kickback Statute and False Claims Act, Plaintiff directs Defendant to Plaintiff's Second Amended Complaint, Plaintiff's initial disclosures, and Plaintiff's briefing in this action, including, but not limited to, Plaintiff's opposition to Defendant's motion to dismiss the Second Amended Complaint.

INTERROGATORY 12: Identify all False Claims that you allege Defendant caused the Phase One Accounts to submit to Medicare for the reimbursement of Remicade and Simponi ARIA.

RESPONSE TO INTERROGATORY 12:

Pursuant to Federal Rule of Civil Procedure 26(a)(1)(A)(iii), Plaintiff's initial disclosures explained that damages will be subject to additional discovery and to expert opinion, and will be disclosed in accordance with the deadlines established by the Court. Plaintiff will rely upon information and documents in the possession, custody, and control of the U.S. Department of Health & Human Services, some of which has been requested in accordance with the Court's phased discovery approach.

Plaintiff objects to this interrogatory to the extent that it seeks an answer that may be determined by examining, auditing, compiling, abstracting, or summarizing the Medicare claims data produced in this action by the Centers for Medicare & Medicaid Services in response to Plaintiff's subpoena and which Plaintiff subsequently produced to Defendant on July 15, 2021, and the burden of deriving or ascertaining the answer will be substantially the same for either party. Plaintiff objects to this interrogatory to the extent that Defendant is seeking to force Plaintiff to prematurely adopt or lock into a legal position.

Subject to the foregoing objections and general objections, Plaintiff responds as follows:

A “claim” is “any request or demand ... for money or property” presented to an officer, employee, or agent of the United States. 31 U.S.C. § 3729(b)(2). Plaintiff alleges that all claims for payment for Remicade, Simponi ARIA, and related infusion procedures that health care providers associated with the Phase 1 Accounts submitted to Medicare on or after October 28, 2010 and after the Phase 1 Account received one or more of the IOI Support services and related programs identified in Plaintiff’s response to Interrogatory 2 constitute claims that were false or fraudulent in violation of 31 U.S.C. § 3729(a)(1)(A) & (B). The illegal remuneration that Defendant provided to the Phase 1 Accounts before and after October 28, 2010, induced the health care providers associated with the Phase 1 Accounts to prescribe and administer Remicade and/or Simponi ARIA infusions to Medicare beneficiaries and likewise resulted in and/or caused the health care providers to subsequently submit false claims to Medicare for the drugs and infusion services. There was a causal connection between the alleged Anti-Kickback Statute violations and the subsequent false claims for reimbursement submitted to Medicare. The Medicare beneficiaries who were prescribed the Remicade or Simponi ARIA infusions by the health care providers associated with the Phase 1 Accounts after the accounts received the alleged illegal remuneration were exposed to an illegal referral, order, or purchase. Plaintiff alleges that the causation requirements for Anti-Kickback Statute violations under First Circuit and District of Massachusetts law are met. The specific billing information concerning false claims that health care providers associated with the Phase 1 Accounts submitted to Medicare between 1998 and May 15, 2021 are included in the Medicare claims data produced to Defendant on July 15, 2021.

INTERROGATORY 13: State the basis for Your contention that the claims identified in Your response to Interrogatory No. 12 were False Claims.

RESPONSE TO INTERROGATORY 13:

To the extent that this interrogatory is requesting that Plaintiff state the evidentiary support for each alleged Anti-Kickback Statute and False Claims Act violation, Plaintiff objects because it is misusing this interrogatory to improperly attempt to obtain a detailed narrative of Plaintiff's case or pretrial memorandum. Defendant has failed to show why the information requested in this Interrogatory is appropriate or necessary at this stage of the litigation. Also, additional documents that support Plaintiff's claims are in the custody, possession, or control of Defendant and some of which are still in the process of being produced and reviewed. Plaintiff also objects to this interrogatory to the extent that Defendant is seeking to force Plaintiff to prematurely adopt or lock into a legal position.

Subject to the foregoing objections and the general objections, Plaintiff responds as follows: *See* Plaintiff's response to Interrogatory 11. The claims submitted to Medicare identified in Plaintiff's response to Interrogatory 12 were false or fraudulent in violation of 31 U.S.C. § 3729(a)(1)(A) & (B) because:

- (a) The claims "include[d] items or services resulting from a violation of [the Anti-Kickback Statute] ..." 42 U.S.C. § 1320a-7b(g). And "an [Anti-Kickback Statute] violation that results in a federal health care payment is a per se false claim under the [False Claims Act]." *United States v. Regeneron Pharm. Inc.*, Civ. No. 20-11217-FDS, 2020 WL 7130004, at *7 (D. Mass. Dec. 4, 2020) (quoting *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019)).
- (b) In the claim, the health care providers falsely represented to Medicare that they had not received illegal remuneration and that they had complied with the Anti-Kickback Statute in

providing and billing for the Remicade, Simponi ARIA, and related infusions. The representation health care providers made in bills submitted on Form CMS-1500 to Medicare regarding compliance with the Anti-Kickback Statute can be viewed at ¶ 28 of the Second Amended Complaint and CMS000005 – CMS000008.

- (c) The health care providers had falsely certified in their provider enrollment agreements with Medicare that they would comply with the Anti-Kickback Statute. The express representation health care providers made in enrollment agreements with Medicare regarding compliance with the Anti-Kickback Statute is publicly available and can also be viewed at ¶ 26 of the Second Amended Complaint. In submitting claims for payment for Remicade, Simponi ARIA, and related infusion services after receiving the services and related programs identified in the response to Interrogatory 2, the health care providers falsely represented that they were complying with the certification made in their enrollment agreements.

INTERROGATORY 14: State the basis for Your contention in Count I, as it relates to the Phase One Accounts, that Defendant “caused the health care providers to present claims for reimbursement to Medicare . . . that were false or fraudulent because the providers violated the Federal AKS and State AKS by accepting the kickbacks from Janssen.”

RESPONSE TO INTERROGATORY 14:

To the extent that this interrogatory is requesting that Plaintiff state the evidentiary support for each alleged Anti-Kickback Statute violation and each corresponding False Claims Act violation involving the Phase 1 Accounts, Plaintiff objects because it is misusing this interrogatory to improperly attempt to obtain a detailed narrative of Plaintiff’s case or pretrial memorandum. Defendant has failed to show why the information requested in this Interrogatory

is appropriate or necessary at this stage of the litigation. Also, additional documents that support Plaintiff's claims are in the custody, possession, or control of Defendant and some of which are still in the process of being produced and reviewed.

Subject to the foregoing objections and the general objections, Plaintiff responds as follows: *See* Plaintiff's responses to Interrogatories 2, 5, 10, 11, 12, and 13. As a result of its knowing and willful offering and provision of the IOI Support services and related programs identified in Plaintiff's response to Interrogatory 2 to induce health care providers associated with the Phase 1 Accounts to prescribe and infuse Remicade and Simponi ARIA to Medicare beneficiaries in violation of the Anti-Kickback Statute, Defendant caused the health care providers associated with the Phase 1 Accounts to present claims for reimbursement to Medicare that were false or fraudulent under 31 U.S.C. § 3729(a)(1)(A). The claims for reimbursement submitted by the health care providers associated with the Phase 1 Accounts were false claims under the False Claims Act because they included items and services (Remicade, Simponi ARIA, and/or related infusion procedures) resulting from violations of the Anti-Kickback Statute. *See* 42 U.S.C. § 1320a-7b(g); *United States v. Regeneron Pharm. Inc.*, Civ. No. 20-11217-FDS, 2020 WL 7130004, at *7 (D. Mass. Dec. 4, 2020) ("an [Anti-Kickback Statute] violation that results in a federal health care payment is a per se false claim under the [False Claims Act].") (quoting *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019)). The claims for reimbursement submitted by the health care providers associated with the Phase 1 Accounts were also false claims under the False Claims Act because the health care providers falsely certified, stated, and/or represented in connection with each claim that they submitted to Medicare on or after October 28, 2010, in which they requested and received reimbursement for Remicade, Simponi ARIA, and/or related infusion services, that the claim complied with the Anti-Kickback Statute.

Compliance with the Anti-Kickback Statute is a requirement for coverage and reimbursement by Medicare; Medicare would not have paid or reimbursed the recipients of the IOI Support for billed Remicade, Simponi ARIA, or the related infusion procedures had it been aware that the health care providers received the illegal remuneration from Defendant in violation of the Anti-Kickback Statute.

In addition, Plaintiff directs Defendant to Plaintiff's Second Amended Complaint and Plaintiff's briefing in opposition to Defendant's motion to dismiss the Second Amended Complaint, and Plaintiff's initial disclosures.

INTERROGATORY 15: State the basis for Your contention in Count II, as it relates to the Phase One Accounts, that "Janssen caused health care providers to make false records or statements that were material to getting false or fraudulent claims paid by Medicare."

RESPONSE TO INTERROGATORY 15:

To the extent that this interrogatory is requesting that Plaintiff state the evidentiary support for each alleged Anti-Kickback Statute violation and each corresponding False Claims Act violation involving the Phase 1 Accounts, Plaintiff objects because it is misusing this interrogatory to attempt to improperly obtain a detailed narrative of Plaintiff's case or pretrial memorandum. Defendant has failed to show why the information requested in this Interrogatory is appropriate or necessary at this stage of the litigation. Also, additional documents that support Plaintiff's claims are in the custody, possession, or control of Defendant and some of which are still in the process of being produced and reviewed.

Subject to the foregoing objections and the general objections, Plaintiff responds as follows: *See* Plaintiff's responses to Interrogatories 2, 5, 10, 11, 12, 13, and 14. As a result of its knowing and willful offering and provision of the services and related programs identified in

Plaintiff's response to Interrogatory 2 to induce health care providers associated with the Phase 1 Accounts to prescribe and infuse Remicade or Simponi ARIA to Medicare beneficiaries in violation of the Anti-Kickback Statute, Defendant, in violation of 31 U.S.C. § 3729(a)(1)(B), caused health care providers to make false records or statements that were material to getting false or fraudulent claims paid by Medicare. More specifically, the health care providers associated with the Phase 1 Accounts falsely certified, stated, and/or represented in connection with each claim that they submitted to Medicare on or after October 28, 2010, in which they requested and received reimbursement for Remicade, Simponi ARIA, and/or related infusion services that the claim complied with the Anti-Kickback Statute. The health care providers associated with the Phase 1 Accounts also falsely represented that they were complying with the obligation under their provider enrollment agreements with Medicare that they were not accepting or receiving remuneration that violated the Anti-Kickback Statute. Compliance with the Anti-Kickback Statute is a requirement for coverage and reimbursement by Medicare; Medicare would not have paid or reimbursed the recipients of the IOI Support for billed Remicade, Simponi ARIA, or the related infusion procedures had it been aware that the health care providers received the illegal remuneration from Defendant in violation of the Anti-Kickback Statute.

In addition, Plaintiff directs Defendant to Plaintiff's Second Amended Complaint and Plaintiff's briefing in opposition to Defendant's motion to dismiss the Second Amended Complaint, and Plaintiff's initial disclosures.

INTERROGATORY 16: State the basis for Your contention in Counts I and II that the United States was “unaware” that Janssen provided in-office infusion support services.

RESPONSE TO INTERROGATORY 16:

Plaintiff objects to this interrogatory because the information it seeks is not relevant to any claim or defense asserted in this action.

Subject to the foregoing objections and general objections, Plaintiff responds as follows: In Counts I and Counts II, Plaintiff alleged that the United States was “unaware of the foregoing circumstances and conduct.” Plaintiff is not aware of evidence demonstrating that, before Plaintiff commenced this action, the United States was aware of the alleged circumstances and conduct underlying Counts I and II, including that Defendant knowingly and willfully regularly offered and provided the free IOI Support services and related programs identified in Plaintiff’s response to Interrogatory 2 and alleged in the Second Amended Complaint (directly and indirectly through outside consultants) to select physician practices to induce the physicians to purchase, order, and infuse Remicade and/or Simponi ARIA to patients including Medicare beneficiaries.

DATED: August 9, 2024

/s/ Casey M. Preston

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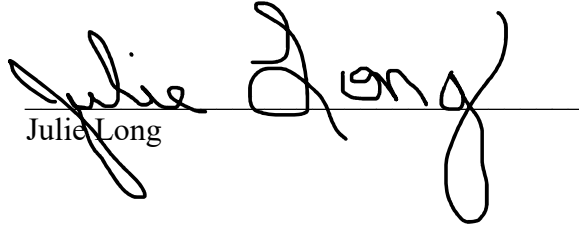
Counsel for Plaintiff Relator Julie Long

VERIFICATION

I am the plaintiff-relator in this action and have reviewed the foregoing supplemental responses to Defendant's Interrogatories 11 to 16.

I verify under penalty of perjury that the factual statements contained in the foregoing supplemental responses to Defendant's Interrogatories 11 to 16 are true and correct to the best of my knowledge, information, and belief.

Executed on August 9, 2024


Julie Long

CERTIFICATE OF SERVICE

I hereby certify that on August 9, 2024, a copy of the foregoing Plaintiff's Supplemental Objections and Responses to Defendant's Interrogatories 11 to 16 was served electronically on the following counsel:

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/s/ Casey M. Preston

Casey M. Preston

APPENDIX A

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JANSSNBIO-068-00004720	Appendix A (8.19.2022 Prod.)	XCE-CID0001174	XCE-CID0001597
JANSSNBIO-068-00004721	Appendix A (10.14.2022 Prod.)	XCE-CID0001175	XCE-CID0001599
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